No. 78-605

FOR ARGUMENT

In the Supreme Court of the United States

OCTOBER TERM, 1978

UNITED STATES OF AMERICA, et al.,

Petitioners,

vs.

GLEN L. RUTHERFORD, et al.,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Tenth Circuit

BRIEF OF THE NATIONAL HEALTH FEDERATION, AMICUS CURIAE, IN SUPPORT OF RESPONDENTS

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The National Health Federation and Laetrile Availability

The National Health Federation is a California not-for-profit corporation, and is America's largest, non-commercial health consumer group. It was founded in 1955, and its membership is comprised of men and women in all walks of life, belonging to a variety of religious faiths and

political persuasions, and engaged in nearly every profession and trade. Its members believe that health freedoms are inherently guaranteed to us as human beings, and our right to them as Americans is implied in the words, "life, liberty and the pursuit of happiness". The National Health Federation and the 80,000 or more persons it represents oppose monopoly and compulsion in matters related to health and nutrition. In particular, the Federation and its membership believe in the "freedom of choice" now, and always, exercised by American citizens as to their health, and oppose "medical dictation" of any type whatsoever from Washington, D.C., or elsewhere.

"Freedom of choice", when applied to the instant cause, encompasses the freedom of the terminally ill, members of the respondent class, and, in fact, everyone, to choose between existing therapies for the treatment of cancer.

The Federation also believes that such choice between the highly toxic and largely ineffective orthodox cancer therapies, and the non-toxic therapy of treatment with Laetrile, as included in an overall "metabolic therapy" program, lies within the Constitutionally protected right of privacy, allowing members of the Respondent class, and others, to make said choice free from government intervention, and bureaucratic dictation.

Accordingly, The National Health Federation, in light of its long-standing involvement with the issues encompassed herein as to freedom of choice, the primary principle upon which said organization was founded, presents its brief *amicus curiae.*

SUMMARY OF THE ARGUMENT

Lower Court Decisions

The lower Court decisions herein quite properly protect the respondent class of terminal cancer patients from FDA interference with their use of Laetrile.

Cancer — The Underlying Problem

The federal government's own statements and statistics demonstrate that we are not winning the battle against cancer, but losing it very rapidly, the conventional therapies being totally inadequate to handle the problem.

Petitioner Discriminates with a "Double Standard" of Safety

Whether or not due to its implacable opposition to Laetrile over the years, FDA has not even-handedly and nondiscriminatorily applied to Laetrile the same standards by which it has measured other anti-cancer drugs for "safety" and "efficacy", thereby approving many very toxic, grossly dangerous, even lethal and fatal drugs in the name of "safety".

"Consensus of Ignorance" No Substitute for Scientific Expertise

No provision of the Federal Food, Drug, and Cosmetic Act provides that merely because "experts" know nothing of a substance, that this obviates "general recognition" by those who are actually qualified to express an opinion.

Laetrile — No Issue as to Its Chemical Identity

The Commissioner himself, in his decision on the status of Laetrile, recognized that the term Laetrile is used interchangeably with amygdalin, nitriloside, and Vitamin B-17.

No "Efficacy" Requirement — 1962 Grandfather Clause

FDA's attempt to read efficacy into the requirements of the 1962 grandfather clause would lead to the anomalous result that an individual suffering from a life-threatening disease for which there exists no known "effective" treatment, would not be lawfully entitled to any treatment at all since no drug could qualify under FDA's interpretation of the Act.

FDA Ignores Value of Laetrile

FDA ignores recognized clinical investigations denoting the value of Laetrile.

FDA Attempts to Destroy State Laws by Bureaucratic Fiat

FDA ignores, and by silence implies the nonexistence of a very important circumstance, namely the passage by nineteen States thus far of laws specifically permitting and approving the use of Laetrile.

Laetrile Denied to the States

The state Laetrile laws thus far enacted will have little actual value due to the breadth and scope of the commerce clause.

FDA Opposition to Laetrile Not Based Upon Science

FDA opposition to Laetrile has precluded a scientifically based review by the Agency.

Respondent Rutherford, et al. — No Means or Resources To Follow "New Drug" Procedures

Lack of resources and time, due to the terminal nature of his disease, preclude the terminally ill cancer patient

from pursuing FDA's "New Drug Application" procedures.

Important Constitutional Rights Involved

The FDA has failed to exhibit a "compelling state interest", in order to justify the interference with respondents' Constitutionally protected rights of privacy.

Individual Rights Recognized by Court Below

The U. S. District Court properly recognized and applied guaranteed Constitutional rights of privacy to the case at bar.

FDA Reaches Back to the Middle Ages to Ban Laetrile

FDA's review of Drug Regulation in its "Appendix A" is inapropos and ignores the numerous instances wherein bureaucracy has deprived mankind of progress in the drug field.

ARGUMENT

Lower Court Decisions

Elsewhere herein the Court has been duly advised of the decisions of the U. S. District Court for the District of Oklahoma and the U. S. Court of Appeals for the Tenth Circuit, respectively, whereby such decisions protect the respondent class of terminal cancer patients from interference by FDA as to the Laetrile which they value very highly. Indeed, certain persons in such class, such as respondent Glen Rutherford, depend upon the same for their very lives.

Heretofore the U. S. District Court for the District of Oklahoma, Honorable Luther Bohanon presiding, has ruled extensively concerning the legal status of Laetrile, these rulings having followed a so-called "rule-making" proceeding of FDA, previously ordered by the U. S. Court of Appeals for the Tenth Circuit and the U. S. District Court in prior rulings, and reluctantly acceded thereto by FDA.

The December, 1977 opinion of the District Court (Pet. App. 11-44A) is reported at 438 F. Supp. 1287, and was, in summary:

1. That Laetrile, on October 9, 1962 (and, therefore, thereafter) was "generally recognized as safe" and met the other criteria of the 1962 "Grandfather Clause" to the Federal Food, Drug, and Cosmetic Act, and therefore is a drug proper and legal for distribution in interstate commerce.

2. That there is a Constitutional "right of privacy" which attaches to Respondent Glen Rutherford, and the others of the class action group of plaintiffs who have

brought the within action, as well as to those not specifically members of that class, which bars FDA from interfering with their use of Laetrile.

The Federation considers the U. S. District Court opinion and ruling in question to be well-reasoned, exhaustive and definitive in all respects, and adopts the ruling of said lower Court in all respects as though set forth herein in full in this amicus curiae brief.

The Federation further notes to the Court that FDA herein does not seek to limit availability of Laetrile to terminal cancer patients, or even any other designated class of persons, but by the ruling it seeks from this Court would bar Laetrile to everyone, no matter what their position or condition.

If the petitioner agency is successful herein in its plea to the Court, namely that no one, not even a terminal cancer patient, may receive Laetrile in any form, thousands of patients now dependent upon Laetrile, and presently protected by the decrees of the District Court below and the 10th Circuit U. S. Court of Appeals, will be effectively left to die without the treatment they now value for their very lives.

Cancer — The Underlying Problem

Basic to the arguments being presented to the Court by petitioner herein is the "rosy", but totally unjustified "imputation" that with orthodox, or conventional, cancer therapies we are rapidly winning the battle against cancer, and that, therefore, we need look no further to such therapies as those afforded by Laetrile, and its accompanying metabolic therapies as employed by physicians throughout the United States, and over the World. However, the government's own statements and statistics demonstrate that

we are not winning the battle against cancer, but losing it very rapidly, the conventional therapies being totally inadequate to handle the problem.

In 1977, 400,000 Americans died of cancer, a figure which is seven times the total fatalities in the Vietnam and Korean wars. According to Dr. Marvin Schneiderman, Associate Director of the National Cancer Institute, a government agency which receives approximately $800,000,000.00 per year in taxpayers' funds, the death rate from all types of cancer is continuing to increase. Dr. Schneiderman also states that cancer mortality, overall, is increasing, so that it is the only major cause of death which has continued to rise from 1900 through 1976. Putting it another way, more people are dying today from cancer in every age group than have died from cancer in such age groups at any other time in American history. According to present projections 1 in 4 Americans is doomed to die of cancer. Pursuant to the best available government statistics, the cancer death rate in 1900 was *64* per 100,000 of the population, a figure which has now increased to *162.8* per 100,000, or almost a three-fold increase. As recently as 1965, the cancer death rate per 100,000 persons was only *127.9*. Within the overall statistics, there are equally unfavorable figures as to specific types of cancer. For example, between 1973 and 1975, the number of lung cancer cases increased in the United States 13%, breast cancer, 17%, stomach cancer, 28%, and prostate cancer, 32%, for the same period. Nor is median survival time particularly encouraging for the cancer sufferer. According to the U. S. Department of Health, Education, and Welfare, the observed median survival time in approximately 219,500 cases of cancer (all sites) was *1.7 years*. This median survival time includes those cases wherein a cancer is localized, or limited to the site of origin.

Of great interest to the matter at bar, however, are the statistics concerning distant (disseminated or "metastasized") cancer, wherein the U. S. Government has stated that the five-year relative survival rate ranges from a maximum of 17% for prostate cancer, to 14% for corpus uteri cancer, 12% for cervix cancer, 10% for female breast cancer, 8% for ovary cancer, 5% for colon cancer, 4% for rectum and bladder cancer, 2% for stomach cancer, 1% for lung and bronchus cancer, and a "zero" survival rate for pancreas cancer for that period. The overall death rate for those afflicted by distant or disseminated cancers, after a period of five years, is *91%*.[1]

Respondents consider this latter figure to be of particular significance herein, due to the fact that the respondents, together with thousands of other patients who have availed themselves of Laetrile or amygdalin are "terminal", namely, no conventional therapy is of any avail to prolong their lives beyond the dismal life span heretofore shown by the government's statistics, and which inescapably reflect the inadequacy and inefficacy of conventional cancer therapies. Thus, respondent Rutherford and those others who have petitioned the Courts, and who also have

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[1] See testimony of Dr. Marvin Schneiderman, Associate Director, National Cancer Institute, March 5, 1979, before Special Subcommittee, U. S. Senate, Edward Kennedy, Chairman; "Facts of Life and Death", U. S. Department of Health, Education and Welfare Publication No. (HRA) 74-1222; "Mortality Trends for Leading Causes of Death", U. S. Department of Health, Education, and Welfare Publication No. (HRA) 74-1853; "Ca-A Cancer Journal for Clinicians"; "Cancer Rates and Risks", 2nd Edition, U. S. Department of Health, Education, and Welfare Publication No. (NIH) 75-691.

been recognized by the legislatures of 19 states to date, believe that Laetrile offers hope as against virtually no hope whatsoever from conventional therapies.

In this connection the petitioner agency apparently believes that cancer patients should willingly and cheerfully die, rather than have Laetrile. In the Administrative Rule Making Hearing on Laetrile, held by FDA on May 2, 1977, Dr. Samuel C. Klagsbrun participated on behalf of the Agency. (Hrg. transcript, page 60, et seq.)

Dr. Klagsbrun is a psychiatrist who was instrumental in setting up an auspice for dying patients. Although a medical doctor, Dr. Klagsbrun does not treat his patients to get them well, but specializes in "helping cancer patients to die". Concerning conventional therapies for cancer, Dr. Klagsbrun stated (page 65): "the odds are slim, we know that, you are not talking to somebody who thinks it is a terrific thing that we have." Nevertheless, Dr. Klagsbrun proudly testified as to successfully discouraging cancer patients from seeking alternate therapies in Mexico, or elsewhere, and in two instances which he noted had been "successful" in convincing the terminal cancer patient to die rather than opt for an alternative therapy.

This conclusion that cancer patients should willingly die rather than seek alternate therapies lies at the heart of what is involved herein. When somebody is terminally ill from cancer, when orthodox treatments can offer nothing, then the terminal cancer patient has the inalienable right and final choice to choose between Dr. Klagsbrun's "success" in dying, and an alternate cancer therapy, involving Laetrile, after informed consent by the administering physician.

Petitioner Discriminates with a "Double Standard" of Safety

The District Court, upon reviewing the voluminous record before the petitioner agency herein determined that Laetrile, or amygdalin, was "safe" and "generally recognized as safe", criteria applied in the Court's ruling that Laetrile is "grandfathered" pursuant to the applicable provisions of the Federal Food, Drug, and Cosmetic Act.

In an attempt to reverse these findings of the District Court, petitioner herein represents to this Court that somehow Laetrile is "not safe", but "toxic" (in the oral form, at least), and that therefore Laetrile does not meet the strict standards of "safety" which are a prerequisite to Food and Drug Administration approval of any anticancer drugs. (See, for example, pages 9, 14, and 46, petitioner's brief).

Not only are the District Court's findings on "safety" attacked by FDA here, but, likewise, the decision of the U. S. Court of Appeals for the Tenth Circuit, characterized by petitioner as stating that "FDA had failed, in the court's view, to advance a standard against which to measure the safety and effectiveness of Laetrile with respect to such patients . . ." (page 13).

Despite voluminous legal citations in its brief on "safety", also efficacy", it is indeed true, nevertheless, that nowhere does FDA indicate, practically and factually, what such standards might be, to be applied by this Court.

In recognition, perhaps, of the inadequacy of the record before the District Court to merit such an attack on the safety of Laetrile, petitioner's brief contains numerous references to matters not actually before the District Court, but consisting of reports in outside "medical literature". For example, at page 9 of its brief, petitioner cites several

such "reports" as to the oral Laetrile, including the alleged death of an eleven-month-old girl who is stated to have ingested amygdalin tablets. As to this alleged fatality, however, petitioner does not reveal to the Court that the hospital records underlying this particular case do not disclose that the child in question ever had amygdalin or "Laetrile" in any form!

Also cited by petitioner (page 9 of its brief) is a "dog study" wherein various dogs, previously tranquilized, were "force-fed" massive amounts of amygdalin, through tubes, the tranquilized dogs predictably succumbing to these pre-planned circumstances. At least one Court has found this so-called "study" to be of questionable validity.[2]

Although petitioner attempts to lump together the oral and injectible forms of Laetrile, and attacks the "safety" of this injectible form of amygdalin, once again employing "outside medical literature", the actual toxicity stated (page 9 of its brief) is limited to "A Report of Two Cases" reported in the Journal of the American Medical Association in 1977, and allegedly involved "symptoms of rash, fever, malaise, headache, and severe abdominal cramps" which disappeared upon discontinuance of Laetrile in those two cases.

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[2] See *In the Matter of JOSEPH HOFBAUER,* Family Court, County of Saratoga, New York, 1978, affirmed 411 N.Y.S. 2d 416 (December, 1978) and wherein the Court found "25. That petitioners produced one expert who claims that as a result of a study of 10 dogs he determined that amygdalin (Laetrile) was toxic. This court finds that that study was of questionable validity and that in fact amygdalin (Laetrile), although toxic, as are all substances, is, for the purposes of this proceeding, a non-toxic substance, the scientific evidence clearly demonstrates that on the issue of toxicity amygdalin (Laetrile) is clearly less toxic than the drugs used in conventional therapy."

Opposed to this very limited "anecdotal" report is the experience of thousands of cancer patients throughout the United States who have received and are receiving Laetrile with complete safety.[3]

Concerning the criterion of "safety" urged by petitioner to be applied by this Court as to the instant cause, it is stated (page 31 of its brief):

> "A drug is 'safe', within the meaning of the Act, if the benefits expected to be achieved through its administration outweigh the costs of risks incurred."

Presumably, therefore, FDA has applied and applies these standards of "safety" in numerous instances whereby anticancer drugs have been approved by the Agency for use by physicians, and for administration to cancer patients. However, in the instance at hand, and whether or not due to its implacable opposition to Laetrile over the years, FDA has not even-handedly and non-discriminatorily applied to Laetrile the same standards by which it has measured other anticancer drugs for "safety" and "efficacy".

Whereas for quite minor reasons FDA attacks herein the "safety" of Laetrile, even attempting to reverse the findings of the District Court on such subject, nevertheless, by applying a "double-standard" of such criterion, many very toxic, grossly dangerous, even lethal and fatal drugs have been approved in the name of "safety" by the Agency.

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[3] For example, Dr. Bruce Halstead, a California physician, biotoxicologist, academician, and researcher, has noted that as to amygdalin or "Laetrile", "Upwards of 75,000 people are taking somewhere in the vicinity of an excess of one million grams of laetrile a month in the United States", with safety. Dr. Halstead further described the toxicity of various conventional anticancer drugs as being "practically at war gas level". (See aforesaid case of *In re HOFBAUER.*)

To designate these circumstances, respondents consider it only proper that they should make reference to authoritative medical literature, in particular concerning FDA-approved "safety" standards as to other anticancer drugs. In this regard, respondents refer to the publication "Physicians' Desk Reference", 33rd Edition, 1979.[4]

CYTOXAN (Mead Johnson & Co.) A dangerous drug which can cause death. This FDA-approved "anticancer" drug actually can also cause cancer, namely secondary malignancies. According to the FDA-approved "safety" data: "the possibility of secondary malignancy, based on available data, should be considered in any benefit-to-risk assessment for the use of the drug." In addition to causing cancer and death, numerous side-effects can occur from this drug, including destruction of immune systems, leukopenia, hemorrhage, gonadal suppression, resulting in amenorrhea or azoospermia, possibly "irreversible". The drug is not represented to be cancer-curative. See Exhibit A herein, page 18.

ADRIAMYCIN (Adria Laboratories Inc.) The FDA-approved data on "safety" states that special attention

[4] This is a standard reference work for doctors, wherein each product description has been prepared by the manufacturer, and edited and approved by the manufacturer's medical department, medical director, and/or medical consultant. Any products described in such publication which have official package circulars must be in full compliance with Food and Drug Administration regulations pertaining to labeling for prescription drugs, and any "indications, effects, dosages, routes, methods, frequency and duration of administration and any relevant warnings, hazards, contraindications, side effects, and precautions" must be in the "same language and emphasis" as the FDA-approved labeling for the product. (See Exhibit A herein, pages *1 and 2*)

"must be given to the cardiac toxicity" exhibited by this drug. Such labeling data further states that "Congestive heart failure and/or cardiomyopathy may be encountered several weeks after discontinuation" of therapy with this drug, and that cardiac failure is often "not favorably affected by presently known medical or physical therapy for cardiac support." According to such labeling, there is a "high incidence of bone marrow depression" and administration of the drug "may result in superinfection or hemorrhage." Numerous severe and body-damaging adverse reactions are also listed in the approved labeling, including acute nausea and vomiting, phlebosclerosis, severe cellulitis, vesication and tissue necrosis (death), fever, chills and anaphylaxis. The drug is not stated to be cancer-curative. (See Exhibit A herein, page 3).

ADRUCIL (Adria Laboratories Inc.) According to the manufacturer's FDA-approved "safety" data, this is a "highly toxic drug with a narrow margin of safety." It is further stated that "severe hematologic toxicity, gastrointestinal hemorrhage, and even death may result" from use of this drug, despite "meticulous selection of patients and careful adjustment of dosage." "Myelosuppression" (bone marrow suppression, particularly spinal) "almost uniformly accompanies a course of adequate therapy" with this drug, according to the aforesaid approved FDA labeling. Other and severe dangerous effects are also described in such labeling. The alleged benefits are stated to be "palliative" (i.e., "affecting relief, not cure".[5]) (See Exhibit A herein, page 4).

[5] *Dorland's Illustrated Medical Dictionary,* 25th Edition.

BICNU (Bristol Laboratories, Division of Bristol Myers Co.) According to the FDA-approved "safety" data for this drug, "delayed bone marrow toxicity is the major toxicity". Other and serious side effects and adverse reactions are also listed. Additionally, the drug causes cancer, the FDA-approved labeling stating "BICNU is carcinogenic in rats and mice, producing a marked increase in tumor incidence in doses approximating those employed clinically." Alleged "benefits" are stated to be "palliative". (See Exhibit A herein, page 6.)

CeeNU (Bristol Laboratories, Division of Bristol Myers Co.) The FDA-approved "safety information" for this drug lists as the "major toxicity" delayed bone marrow suppression. The official labeling also lists cumulative myelosuppression as an effect which can result from this drug. It is also stated: "Neurological reactions such as disorientation, lethargy, ataxia" (failure of muscular coordination) "and dysarthria" (impaired speech) "have been noted in some patients receiving CeeNU." Alleged " benefits" are stated to be "palliative". (See Exhibit A herein, page 10.)

DTIC (Dome Division, Miles Laboratories, Inc.) The "safety" data approved by FDA for this drug states: "Leukopenia and thrombocytopenia may be severe enough to cause death." According to FDA-approved labeling, more than 90% of patients are affected with the initial few doses as to anorexia, nausea and vomiting, among other things. The drug is not stated to be cancer-curative. (See Exhibit A herein, page 13.)

MUTAMYCIN (Bristol Laboratories, Division of Bristol Myers Co.) The FDA-approved "safety" data for this product states: "Bone marrow suppression, notably thrombocytopenia and leukopenia, which may contribute to overwhelming infections in an already compromised patient, is the most common and severe of the toxic effects of Mutamycin." Elsewhere in the FDA-approved labeling, it is stated that such bone marrow toxicity occurred in 64.4% of a group of patients tested. It is also stated that: "About 25% of the leukopenic or thrombocytopenic episodes did not recover" (i.e., died). Among the other "undesirable side effects" listed in the FDA-approved labeling are "headache, blurring of vision, confusion, drowsiness, syncope" (i.e., temporary suspension of consciousness), "edema, thrombophlebitis, hematemesis, diarrhea, and pain." In addition, this "anti-cancer" drug causes cancer, with an increase of 50% to 100% in cancer tumors, the official FDA-approved labeling stating: "Mutamycin has been found to be carcinogenic in rats and mice. At doses approximating the recommended clinical dose in man, it produces a greater than 100 percent increase in tumor incidence in male Sprague-Dawley rats, and a greater than 50 percent increase in tumor incidence in female Swiss mice." This drug is not alleged to be cancer-curative. (See Exhibit A herein, page 11.)

MATULANE (Roche Laboratories.) In addition to numerous adverse reactions which are caused by this drug, it is also cancer-causing. According to the FDA-approved "safety" data, leukemia, among other things, has resulted from "Matulane therapy". Animal tests reveal other forms of cancer caused by administration of the drug, according to the approved labeling. (See Exhibit A herein, page 23.)

MITHRACIN (Manufactured by Pfizer Laboratories for the Dome Division, Miles Laboratories, Inc.) The FDA-approved "safety" data for this product states: "Severe

thrombocytopenia, a hemorrhagic tendency and even death may result from the use of Mithracin." It is further stated that a detailed analysis of the clinical data in 1,160 patients treated with the drug "indicates that the hemorrhagic syndrome is dose related." The manufacturer also notes, with FDA approval, that with recommended "doses of 30 meg/kg/day or less for 10 or fewer doses" there is an "associated drug-related mortality rate of 1.6%" (16 patients per 1,000 receiving the drug are killed by the drug, in other words, not their cancer). The FDA-approved death rate from this drug rises to 5.7% (or 57 per 1,000) however, with a higher dosage of "Mithracin" noted in said approved labeling. The approved labeling also designates a veritable host of other dangerous side effects. The drug is not stated to be cancer-curative. (See Exhibit A herein, page 14.)

FUDR (Hoffman LaRoche, Inc.) According to the FDA-approved official labeling in effect as of August 1, 1978: "Severe hematological toxicity, gastro-intestinal hemorrhage and even death may result from the use of FUDR despite meticulous selection of patients and careful adjustment of dosage . . . fatalities may be encountered occasionally even in patients in relatively good condition." Numerous other adverse effects of this dangerous drug include functional gastrointestinal, mucosal gastrointestinal, hematologic, dermatologic, miscellaneous clinical reactions, laboratory abnormalities and procedural complications of regional arterial infusion, nausea, vomiting, diarrhea, enteritis, stomatitis, and localized erythema, anemia, leukopenia, and others. Alleged "benefits" are stated to be "palliative". (See Exhibit A herein, page 22.)

FLUOROURACIL (Hoffman LaRoche, Inc.) The official FDA-approved "safety" labeling in effect as of August 1, 1978 states: "Severe hematological toxicity, gastrointestinal hemorrhage and even death may result from the use of Fluorouracil despite meticulous selection of patients and careful adjustment of dosage." Numerous other adverse and dangerous reactions and side effects are also listed in such official labeling. Alleged "benefits" are stated to be "palliative", only. (See Exhibit A herein, page 20.)

METHOTREXATE (Lederle Laboratories.) The "safety" data contained in the FDA-approved labeling for this product states that "sudden death has been reported from use of Methotrexate." It is also stated that the drug "may produce marked depression of bone marrow, anemia, leukopenia, thrombocytenopenia and bleeding", it may be "Hepatotoxic" (liver damaging) and cause "liver atrophy, necrosis" (death), "cirrhosis, fatty changes, and periportal fibrosis". It is also stated that this drug, approved by FDA for its "safety", may have an "immunosuppressive action" (i.e., destroying the immune systems of the body). Listed as "common adverse reactions" are included ulcerative stomatitis, leukopenia, nausea and abdominal distress, malaise, decreased resistance to infection, depigmentation, alopecia, hemorrhage from various sites, vomiting, diarrhea, gastrointestinal ulceration and bleeding, renal (kidney) failure, infertility, abortion, severe nephropathy (kidney disease), blurred vision, paresis (paralysis) and convulsions, ataxia, dementia, precipitating diabetes, osteoporotic effects (calcium leached from the bones), abnormal tissue cell changes, and others. The drug is not stated to be cancer-curative. (See Exhibit A herein, page 16.)

BLENOXANE (Bristol Laboratories, Division of Bristol Myers Co.) The FDA-approved "safety" data for this product states: "Pulmonary fibrosis" (i.e., progressive fibrous degeneration of the lung) "is the most severe toxicity associated with Blenoxane." It is further stated that in approximately 1% of patients treated with Blenoxane, "the nonspecific pneumonitis induced by Blenoxane progresses to pulmonary fibrosis, and death. Although this is age and dose related, the toxicity is unpredictable." The same FDA-approved mortality data is repeated elsewhere: "Approximately 1% of patients treated have died of pulmonary fibrosis." Numerous other dangerous and harmful effects of this drug are also listed in the FDA-approved representations. The drug is not stated to be cancer-curative. (See Exhibit A herein, page 8.)

The foregoing illustrate the nature and type of anticancer drugs approved by the petitioner agency for "safety" and "efficacy". Are any of these drugs curative of the cancer conditions for which they are offered? If so, the FDA-approved labeling is devoid of any such claims or representations. And, does a mere "palliative" or "relieving" effect, temporary at best, of a drug justify imposing upon an innocent cancer patient body-destroying, even death-dealing effects from drugs which may, in and of themselves, cause cancer, adding to the plight of the already diseased patient? Respondents respectfully urge that this Court shall apply the rule of common sense to the criteria urged upon the Court as to Laetrile, and concerning which the same is totally "non-toxic", and "safe", if only judged by the standards heretofore applied by FDA as to approved drugs now available and employed by doctors for their cancer patients.

Small wonder that thousands of cancer patients throughout the United States have opted to avoid the deadly effects of FDA-approved cancer drugs in favor of Laetrile, and small wonder that the legislatures of 19 states have perceived the need for cancer patients to have made available to them Laetrile, or amygdalin, in lieu of the ineffective and deadly drugs now available through orthodox medical channels.

"Consensus of Ignorance" No Substitute for Scientific Expertise

In attempting to reverse the District Court's finding that Laetrile, or amygdalin, was "generally recognized as safe" on October 9, 1962 (a criterion for holding that Laetrile is "grandfathered", and therefore may be distributed without interference by FDA), petitioner, at page 46 of its brief, states that in 1962 there was no such "general recognition of safety", because "Laetrile was not generally known at all to the community of medical experts".

In the first place, there is no "community" of scientists or doctors, any more than there is a "community" of lawyers, teachers, butchers, or other professional persons, speaking in "unison", so to speak, on a given subject.

Whatever the case, no provision whatsoever of the Federal Food, Drug, and Cosmetic Act provides that merely because "experts" know nothing of a substance, that this obviates "general recognition" by those who are actually qualified to express an opinion.

Section 201 (p) of the Federal Food, Drug, and Cosmetic Act, as in effect on October 9, 1962, designated a criterion of "general recognition of safety" by "experts

qualified by scientific training and *experience*" to evaluate safety of a substance. (Emphasis supplied) It is respectfully submitted that "ignorance" of a substance cannot under any circumstances be held to constitute the requisite "experience" mandated by the statute, and that, therefore, only an expert having real knowledge of Laetrile would be qualified to express an opinion concerning its safety. Conversely, the opinion of those "ignorant" of Laetrile is of no value whatsoever.

Laetrile — No Issue as to Its Chemical Identity

In its attempt to upset and reverse the findings of the U. S. District Court concerning the "grandfather clause" of the Federal Food, Drug and Cosmetic Act, as applied to "Laetrile", petitioner attempts to delineate to this Court (page 41, et seq.) that somehow there is no identifiable entity which could be termed "Laetrile". This is entirely contrary to fact, even as noted in the Commissioner's Decision on Status" (42 Federal Register, No. 151, Page 39768, et seq.), wherein, the FDA commissioner noted that the Merck Index, 9th Edition, designates "laetrile" as "a term used interchangeably with 'Laetrile', 'amygdalin', 'nitriloside', and 'vitamin B-17'." The record also clearly shows that the chemical identity of "amygdalin" is not new, but has been known to science since at least 1845.

No "Efficacy" Requirement — 1962 Grandfather Clause

After an exhaustive and voluminous review of the entire record, the U. S. District Court found that "Laetrile", or amygdalin, was "grandfathered" as of October 9, 1962, pursuant to the applicable provisions of the Federal Food, Drug and Cosmetic Act, the principal criterion applied in

this regard being that it was, at such time, "generally recognized as safe".

Petitioner would have the Court believe, however, that, although the statute in question does not require "efficacy" as one of the criteria of this "grandfather" provision, that nevertheless this criterion must be applied to Laetrile, and it is therefore barred from distribution.

However, the statutory provisions aforesaid are very clear. If Congress had intended that "efficacy" should be added to "safety" as a necessary component of the 1962 "grandfather clause", it could readily have done so. But, Congress did not. In fact, the "Kefauver Amendments" of 1962, enacted at the same time, *added* an "efficacy provision to the "new drug" definition to apply *after* October 9, 1962. (See Sec. 201 (p) of the statute as presently in force).

Concerning these circumstances, the District Court ruled (See Memorandum opinion and order, April 8, 1977, App. page 53):

> ". . . FDA contends that if laetrile were marketed prior to 1962 it must still be shown to have been 'effective' as well as 'safe' if employed in the treatment of 'a life-threatening disease.' *Durovic* v. *Richardson*, 479 F.2d 242 (7th Cir. 1973). The Supreme Court in *Weinberger* v. *Hynson, supra*, stated that 'the 1962 amendments (of the Food, Drug and Cosmetic Act) for the first time gave FDA power to scrutinize and evaluate drugs for effectiveness as well as safety.' at 630. In any event, the case relied upon by FDA is clearly distinguishable from the case at bar. In *Durovic* v. *Richardson, supra*, the Court held that '(a)ny delay in the institution of effective therapy (e.g., radiation, surgery, effective chemotherapy) caused by the use of an ineffective drug allows the disease to progress

beyond control. Delay means almost certain death.' Significantly, in the present case plaintiff class is comprised of persons already determined to be terminally ill. Adopting FDA's rationale would mean that an individual suffering from a life-threatening disease for which there exists no known effective treatment would not lawfully be entitled to any treatment at all since no drug could be deemed 'generally recognized as effective' in such a situation."

FDA Ignores Value of Laetrile

Whatever technical statutory provisions might apply to Laetrile, it is still worthy of note that it has proven of value to the many thousands of cancer patients and physicians who have employed it in this Country, and elsewhere. Petitioner chooses to ignore such value repeatedly proclaiming Laetrile to be "fraudulent", "useless", "of no value", and the like.

For example, FDA ignores herein a ten-year clinical study of Laetrile conducted by three European scientists (Ettore Guidetti, Christian Deckers, and Benedetto Rossi), the results of which were available to the scientific world as early as 1966, per report of such clinical investigation presented to the Ninth International Cancer Congress, as conducted under the auspices of the International Union Against Cancer. By way of background, this organization includes within its ranks the pre-eminent cancer scientists of the World, including various prestigous orthodox oncologists of the United States.

These European scientists concluded that Laetrile "appears to possess not only a palliative effectiveness, but also a specific and direct action against neoplastic process, peculiarly by local administration without side reactions." 150 cases of "terminal human cancers" were the subject of the clinical investigation, and, as to overall results, the

scientists stated: "We have noticed that the 50% of all cases in treatment showed an objective improvement, proved by many laboratory reports, by x-ray films and by a gain in weight." It was further stated: "We can state that the drug . . . is a suitable one, whether for its therapeutic effectiveness or on account of its extremely low toxicity." (See Exhibit B herein).

Numerous other instances of the value of Laetrile could be cited, also ignored herein by FDA.

In this regard, respondent Rutherford notes that he himself attributes his very life and present good health to Laetrile, a substance which FDA sought to ban him from obtaining, and only made available for his cancerous condition by intervention of the District Court in this proceeding.

FDA Attempts to Destroy State Laws by Bureaucratic Fiat

Throughout its brief Petitioner argues that Laetrile should be denied to everyone because it is a "fraudulent drug", and its mere use constitutes a "fraud".

At Page 68 of its brief, petitioner urges that terminally ill patients or members of the public generally should be denied Laetrile, because they do not have a "Constitutional right of access" to it. And, states FDA further, the right to have Laetrile should be denied "by compelling governmental interests in protecting the public health, reinforced by a legitimate interest in preventing fraud." This ignores, and by silence implies the nonexistence of a very important circumstance, namely the passage by *nineteen States* thus far of laws specifically permitting and approving the use of Laetrile for their citizens, and wherein there is

actually recognition of a "compelling governmental interest" in making available Laetrile in those States.[6]

The nineteen States are: Alaska; Arizona; Delaware; Florida; Idaho; Illinois; Indiana; Kansas; Louisiana; Maryland; Nevada; New Hampshire; New Jersey; North Dakota; Oklahoma; Oregon; South Dakota; Texas; and Washington.[7]

Certain State laws, such as enacted in Illinois, include provisions for "informed consent" to be rendered by the treating physician, and acknowledged by the cancer patient, before treatment with Laetrile commences. In the main these statutes properly equate "Laetrile" and "Amygdalin". All of these State laws were enacted only after extensive hearings, research, and debate. Laetrile legislation is presently pending in various other States. South Dakota is the most recent state to approve Laetrile, its law having been enacted March 16, 1979.

Petitioner's brief contains *not one* word as to these laws!

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[6] Laetrile is, of course, also employed and administered by physicians in various States which have not yet enacted formal legislation.

[7] *Alaska* (See Alaska Statutes 08.64.367); *Arizona* (See A.R.S. 36-2451); *Delaware* (See Del. Code Ann. 16 Section 4901); *Florida* (See F.S.A. 458.24); *Idaho* (See Idaho Code 18-7301A); *Illinois* (See S.H.A. 56½, Section 1801); *Indiana* (See Burns Ind. St. Ann. 16-8-8-1); *Kansas* (See S.B. 505 May 8, 1978); *Louisiana* (See L.S.A.—R.S. 40:676); *Maryland* (See Ann. Code of MD, Art 43 Sec. 133 ch 809); *Nevada* (See Nev. Rev. St. 630.303); *New Hampshire* (See R.S.A. 329:30); *New Jersey* (See N.J.S.A. 24:6F-1); *North Dakota* (See H.B. 1214 eff. July 1, 1979); *Oklahoma* (See 63 Okl. St. Ann. Sec. 2-313); *Oregon* (See Oregon Rev. St. 689.885); *South Dakota* (Bill Number 1287 signed 3/16/79 eff. 7-1-79); *Texas* (See Vernon's Ann. Civ. St. 71 art. 4476-5a.); *Washington* (See R.C.W.A. 70.54.130).

Laetrile Denied to the States

Despite the widespread, definitive State Laetrile legislation noted above, FDA seeks, nevertheless, by banning any interstate distribution of Laetrile, *per se*, or even any substance containing it and from which it may be extracted, to thwart and render of no effect the laws of any state making available Laetrile to its citizens.[8]

Rather obviously, without Laetrile being available, the cancer patient and his Doctor, even though under sanction of an appropriate State law, are barred from its use if none is available and FDA governmental dictates are employed to insure such prohibition.

In an obvious attempt to mute and avoid these clear implications, petitioner's brief states (page 45): "no provision of Federal law directly prohibits personal use or affects any supply that has neither been imported nor had any connection with interstate commerce."

This covert and carefully chosen language ignores the breadth and scope of the commerce clause of the U. S. Constitution, even only as developed since *Wickard* v. *Filburn*, 317 U. S. 11 (1942), legalities followed in the food and drug area.

In *Palmer* v. *U. S.*, 340 F.2d 48 (5th Cir. 1964), the Court held for example, that the shipment of the active ingredient of a drug (in the case at bar, "amygdalin") is

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[8] Amygdalin or Laetrile occurs naturally in approximately twelve-hundred different fruits, vegetables, grains and seeds, including apricot kernels, strawberries, macadamia nuts, lima beans, barley, rye, apple seeds, peach kernels and cherry pits. See *Millet, Pit and Seed Co.* v. *U. S.*, 436 F. Supp. 84 (E.D. Tenn. 1977). The best food substance for extraction of its Laetrile component is apricot kernels, the major U. S. source of which is the State of California.

the equivalent of shipping the drug. Cf. *U. S.* v. *40 Cases More or Less, of Pinocchio Brand 75% Corn, Peanut Oil Blended with 25% Pure Olive Oil,* 289 F.2d 343 (2nd Cir. 1961); *U. S.* v. *39 Cases, More or Less, Mich. Brand Korleen Tablets,* 192 F. Supp. 51 (N.D. Mich. 1961).

Thus, even if one in a State having Laetrile-enabling legislation desired to import through interstate channels an amygdalin containing substance from which to extract Laetrile, the petitioner agency could, under the circumstances it urges herein, and would, ban such importation.

That such bureaucratic procedure would effectually thwart, and render of no effect, the Laetrile laws of any State cannot be doubted. Of interest in this connection is the following excerpt from *Laetrile: The Battle Moves Into The Courtroom,* 65 A.B.A. Journal 224, 226 (February, 1979):

> "But even if Laetrile cannot be imported or moved in interstate commerce, why can't it be used legally if it is grown and processed locally? First, many states lack either the facilities for processing the drug or the climate for producing it. Alaska, for example, was the first state to legalize its use, and the drug might be in use more commonly there if a legislature could cause apricot trees to grow around the Arctic Circle."

FDA Opposition to Laetrile Not Based Upon Science

From merely reading petitioner's brief herein, one would suppose that the FDA attitude toward Laetrile is scientifically based upon the "rule-making" proceeding which occurred in 1977, upon mandate of the District Court and the U. S. Court of Appeals for the Tenth Circuit.

However, this is not the case, the FDA opposition to Laetrile having long predated any such proceeding.

For example, during a 1974 question-answer session, when former FDA Commissioner Schmidt was asked by reporters whether FDA had tested or will test Laetrile in view of the fact that at least 5,000 persons in the U. S. believe it has helped them, the Commissioner "in a voice heavily laced with sarcasm" replied: "The fact that 5,000 people—or 10,000 people—or 15,000 people believe something—even if they are physicians—does not prove anything."[9]

Even as of 1979 FDA has still not tested Laetrile.

The implacable FDA opposition to Laetrile was duly noted by the District Court as the within cause was commenced in 1975, when, respondent Rutherford's Laetrile having been seized by petitioner, he sought Court intervention. At that time, FDA had conducted no administrative proceeding whatsoever to determine the legal status of Laetrile.

FDA appealed the 1975 District Court decision aforesaid to the U. S. Court of Appeals for the Tenth Circuit, which Court, on October 12, 1976 (App. page 31) upheld the Lower Court, its opinion stating that Laetrile "is not a new drug merely because they" (i.e. FDA) "say it is." The Court ordered an administrative review by FDA, which in turn led to the 1977 rulemaking proceeding in question. In view of the previous bias and prejudice of FDA against Laetrile, the ruling of the Commissioner referred to in petitioner's brief herein was eminently predictable.

Nor has FDA's opposition to Laetrile abated since injunctions were ordered by the District Court and the U. S. Court of Appeals for the Tenth Circuit subsequent

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[9] San Jose, California "Mercury", March 25, 1974.

to such rulemaking proceeding. And, although proclaiming the "need for regulation" of Laetrile, allegedly to prevent "fraud" and other misdeeds, petitioner has not even deigned to carry out the most recent rulings of the U. S. Court of Appeals (582 F. 2d 1234), stating:

> "We are confident that the FDA with all due dispatch will promulgate regulations within the above limitations and as if the drug was found by the Commission to be 'safe' and 'effective' for the limited group of persons here considered."

Respondent Rutherford, et al. — No Means or Resources To Follow "New Drug" Procedures

The District Court held, and properly so, that Laetrile, or amygdalin, is "grandfathered" pursuant to the applicable provisions of the Federal Food, Drug and Cosmetic Act. However, FDA combats this ruling herein, urging to the Court that only through processing of a "new drug application" to be presented to the Agency, can Laetrile be validated for interstate distribution to cancer patients, or anyone else, for that matter.

Although the filing of a "new drug application" seems simple, on the face of it, in all practicality, to follow such procedure for an individual such as Respondent Rutherford, would in effect sentence him and many others to death, due to the fact that neither he nor thousands of other cancer patients would individually have the means or resources with which to pursue the complicated and drawn-out procedures involved therein.[10]

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[10] One industry source has estimated that the average new drug proceeding requires ten or more years in time, and an expenditure of approximately $12,000,000.00 per drug, on an average, before approval thereof, with only a relative handful of drugs being approved each year by FDA for the entire pharmaceutical industry.

In this regard, the District Court made appropriate findings at the very outset of the cause at bar, stating in its Findings of Fact and Conclusions of Law issued August 14, 1975 the following (App. page 24):

> "In this connection the Court finds that laetrile has been in use for a number of years in Mexico and other nations around the world; that the FDA has by its regulations made it impossible for the common man to have an application processed through FDA so that said agency would either approve or disapprove the drug known as laetrile. The Court finds that Congress intended by 21 U.S.C. Sec. 355 that the FDA would on its own initiative and in good faith approve or disapprove the use of laetrile, thereby allowing the courts jurisdiction of the subject matter.
>
> "The Court finds that the FDA has abdicated its duty to make a clear determination of whether the drug laetrile should or should not be placed in commerce though the drug has been in use for many years and thousands of persons have been treated with it.
>
> "The Court finds from the record, testimony and exhibits that laetrile is not lethal in any sense of the word. It is not harmful to the human body and when used in proper amounts under proper control and supervision can effect relief from cancer disease to the satisfaction of many who are privileged to use the same."

And (App. page 27):

> "The Court finds that the plaintiff Rutherford and those similarly situated are wholly without means or resources to comply with the provisions of 21 U.S.C. Sec. 355(b) and that for the plaintiff Rutherford and those similarly situated to be denied the freedom of choice for treatment by laetrile to alleviate or cure

their cancer, was and is a deprivation of life, liberty or property without due process of law guaranteed *by the Fifth Amendment to the Constitution of the United States.*"

Important Constitutional Rights Involved

The record below fails to establish evidence of a "compelling interest" on the part of petitioner FDA sufficient to prevail over respondents' constitutionally guaranteed right of privacy in their choice of Laetrile treatment.

This Court has consistently held that when certain "fundamental rights" are involved, regulation may be justified only by a "compelling state interest," and further, that legislative enactments "must be narrowly drawn to express the legitimate state interests at stake." Roe v. Wade, 410 U.S. 113, at 155.

Petitioner's asserted interests in regulation of Laetrile for use by respondents do not meet the strict test required by this Court. As against the terminally ill cancer patient's right to choose a nontoxic substance for his own health care, petitioner FDA's arguments are not compelling by any standard.

First, petitioners claim that without regulation, consumers of Laetrile will be "harmed" by the resulting postponement of other approved supposedly "effective" methods of cancer treatment. The real fear, apparently, is that cancer patients will unwittingly select Laetrile over orthodoxy. Yet the record below discloses that the vast majority of Laetrile patients first underwent the relevant conventional treatments. 438 F. Supp. 1287, at 1296, n. 18 (1977). *This fact is acknowledged in petitioner FDA's own report on Laetrile.* (R. 507, R. 313 at J 242).

With respect to the argument that the choice of Laetrile may be unwitting or uniformed, the Federation would

point out that the affidavit procedure establishing respondents' class requires an intelligent, informed choice.

Many cancer victims have investigated and evaluated the merits of surgery, radiation therapy or chemotherapy with the aid of competent medical advice and have still made the highly personal choice to try Laetrile; the benefits from orthodox treatment are not considered sufficient, at the very least, to justify the risks which include disfigurement, debilitation, and accelerated death, and even additional cancer caused by the treatment. Respondents are a subgroup of the class of all cancer patients. They alone have been advised that their condition is hopeless, and terminal. As a first or last result, they seek Laetrile. As to them, petitioner can have no interest in regulation.

Petitioner FDA further attacks the credibility of "cures" reported to have been effectuated by Laetrile. The Federation answers here that it has no interest in the promotion of Laetrile as a "cure." This depends upon the individual case. Still, petitioner FDA argues that in various instances, the person involved may never even have had cancer. This claim is specious and unsupported in the record below; it is wholly irrelevant and hardly reassuring to respondents, who unfortunately do have cancer. It can carry no weight with respondent Glen Rutherford, for example, whose proposed surgical colostomy would unalterably have lessened the quality of his life, irrespective of the ultimate outcome of his illness. See, 438 F. Supp. 1287, 1299, n. 25 (1977).

The right of the patient is of such fundamental nature its free exercise may be impinged upon or forbidden only by such Governmental interest as may be a "compelling interest."

The "fundamental" nature of this right derives from its source. It flows from the very nature of man. Justice Brandeis in *Olmstead* v. *United States,* 277 U.S. 438, 478 [72 L.Ed. 944, 956, 48 S.Ct. 564, 572 (1928] stated:

> "The makers of our Constitution undertook to secure conditions favorable to the pursuit of happiness. They recognized the significance of man's spiritual nature, of his feelings and of his intellect. They knew that only a part of the pain, pleasure and satisfactions of life are to be found in material things. They sought to protect Americans in their beliefs, their thoughts, their emotions and their sensations. *They conferred, as against the government, the right to be let alone—the most comprehensive of rights and the the right most valued by civilized men.* To protect that right, every unjustifiable intrusion by the government upon the privacy of the individual, whatever the means employed, must be deemed a violation. . . ." (Italics added.)

Judge Cardozo in *Schloendorff* v. *Society of New York Hospital,* 211 N.Y. 125 [105 N.E. 92, at page 93] stated:

> "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; . . . ."

The right to control one's own body is not restricted to the wise; it includes the "foolish" refusal of medical treatment. Nor is this right limited in its recognition to any single segment of the political, economic, or social thought spectrum.

In commenting upon Justice Brandeis' most valued of rights, the right to be left alone, Chief Justice Burger, in his now well-known dissent in *Application of President & Directors of Georgetown Col.,* 331 F.2d 1010, at page 1017, stated:

> "Nothing in this utterance suggests that Justice Brandeis thought an individual possessed these rights only as to *sensible* beliefs, *valid* thoughts, *reasonable* emotions, or *well-founded* sensations. I suggest he intended to include a great many foolish, unreasonable and even absurd ideas which do not conform, such as refusing medical treatment even at great risk."

Without specific reference to a constitutional basis, the right to choose what may be even a suicidal medical course has been upheld. In *Erickson* v. *Dilgard,* 44 Misc. 2d 27 [252 N.Y.S.2d 705, 706] a New York court sustained the unwilling Jehovah's Witness' objection to a needed blood transfusion despite risk of death. The court there said at page 706:

> ". . . it is the individual who is the subject of a medical decision who has the final say and that this must necessarily be so in a system of government which gives the greatest possible protection to the individual in the furtherance of his own desires."

In *Whalen* v. *Roe,* 429 U.S. 589, this Court considered the New York statutory requirements with respect to prescriptions for "dangerous, legitimate" drugs. The requirement in question was that of notification. The Court balanced the invasion of the zone of privacy against the public's right involved and concluded that with respect to the particular type of drugs involved the statutes were a reasonable exercise of the state's broad police power. In so holding the Court discussed the right of an individual to choice of treatment saying:

> "Nor can it be said that any individual has been deprived of the right to decide independently, with the advice of his physician, to acquire and to use needed medication. . . . Within dosage limits which appellees

do not challenge, the decision to prescribe, or to use, is left entirely to the physician and the patient." (Whalen v. Roe, *supra*, 429 U.S. 589, 603 [51 L.Ed.2d 64, 75-76, 97 S.Ct. 869, 878].)

This Court has held that "a right of personal privacy, or a guarantee of certain areas or zones of privacy, does exist under the Constitution" (*Roe* v. *Wade*, 410 U.S. 113, 152, 35 L.Ed.2d 147, 176).

While only personal rights that may be deemed "fundamental" or "implicit in the concept of ordered liberty" are included in this guarantee of personal privacy (410 U.S. 113, 152, 35 L.Ed.2d 147, 176), in his concurring opinion in the *Roe* case, Justice Douglas recognized that the "freedom to care for one's health and person" does come within the purview of the right to privacy (410 U.S. 179, 213, 35 L.Ed.2d 147, 188). Justice Douglas continued:

> "It is one thing for a patient to agree that her physician may consult with another physician about her case. It is quite a different matter for the State compulsorily to impose on that physician-patient relationship another layer or, as in this case, still a third layer of physicians. The right of privacy—the right to care for one's health and person and to seek out a physician of one's own choice protected by the Fourteenth Amendment—becomes only a matter of theory, not a reality, when a multiple-physician-approval system is mandated by the State.
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> • • •
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> "The good-faith decision of the patient's chosen physician is overridden and the final decision passed on to others in whose selection the patient has no part. This is a total destruction of the right of privacy between physician and patient and the intimacy of relation which that entails." (*Roe* v. *Wade*, 410 U.S. 113, 219, 35 L.Ed.2d 191, 192).

In *Matter of Quinlan* (355 A.2d 647, cert. den. 429 U.S. 922, 1976), the Supreme Court of the State of New Jersey held in a declaratory judgment proceeding that the parent and guardian of an incompetent woman could assert on her behalf her constitutional right to privacy. The Court further held that its decision need not be controlled by the consensus of opinion of physicians who were qualified experts, namely, that withdrawal of the support of a respirator would not conform to standard medical practices and would result in Karen Quinlan's death soon thereafter (355 A.2d 647, 669). The decision on whether or not to remove the respirator properly rested with Karen's parents and attending physicians.

Individual Rights Recognized by Court Below

In its decision rendered in December, 1977 (438 F. Supp. 1287), the U. S. District Court applied the foregoing principles enunciated by this Court, and by other Courts, recognizing the important Constitutional rights enjoyed by respondents.

The opinion states:

> "Unintentionally FDA has wrought needless hardship and expense to countless individuals required to travel to Mexico or Germany in order to utilize Laetrile. If it were more readily available in this country, perhaps many patients currently obtaining the treatment abroad could be persuaded to remain under their doctor's care here and use the substance in conjunction with conventional treatments.
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> "The final consequences are ultimately borne by those whose bodies are the battleground on which cancer's war is waged. Many perceive the drug's acquisition as a life and death matter, and are understandably frustrated and enraged over attempts by their own govern-

ment to deny them the right to decide for themselves questions of such a personal and grave nature."

And:

"When certain 'fundamental rights' are invoked, such as the right of privacy involved herein, regulation may be justified only by a 'compelling state interest,' and legislative enactments 'must be narrowly drawn to express only the legitimate state interests at stake.' *Roe* v. *Wade, supra* at 155. By denying the right to use a nontoxic substance in connection with one's own personal health-care, FDA has offended the constitutional right of privacy.

"The court's decision in this case in no way portends the return of the traveling snake oil salesman. As emphasized earlier, the right to use a harmless, unproven remedy is quite distinct from any alleged right to promote such. FDA is fully empowered under statutory provisions to combat false or fraudulent advertising of ineffectual or unproven drugs. *See* the Food, Drug and Cosmetic Act, Misbranded Drugs and Devices, 21 U.S.C. § 352 (1976); and the Federal Trade Commission Act, Dissemination of False Advertisements, 15 U.S.C. § 52 (1975)."

FDA Reaches Back to the Middle Ages To Ban Laetrile

In an effort to buttress its manifestly unsound legal and Constitutional position herein (presumably premised upon the Federal Food, Drug, and Cosmetic Act, enacted in 1938), the petitioner agency, presents to the Court in "Appendix A" to its brief, an anonymously-authored monograph entitled "History of Drug Regulation", designed to convince the Court that Laetrile is now, and has for centuries, been illegal "quackery" and almost "witchcraft", so to speak. In so doing, FDA reaches back to

statutes enacted as long ago as the year 1266, almost 700 years before enactment of the Act under consideration here.

This constitutes an ambitious, if historically inaccurate, project with regard to the subject matter actually before the Court, and the Federation deems it only proper that brief comment should be rendered concerning the same.

It is the overall import of "Appendix A" aforesaid that, without the statutory regulation supposedly invoked from time to time over the past some 700 years, mankind would have been deprived of the bureaucratic protection so necessary for health and welfare.

However, totally omitted from "Appendix A" are the numerous instances wherein bureaucracy has deprived mankind of progress, and, had it not been possible to overcome the bureaucratic dictation and even persecution of those who sought to advance medicine, and human health, we would now be, healthwise, in the same Middle Ages from which Appendix A derives its original citations.

Have we forgotten that there was a time when the best science concluded that the World was flat, the sun revolved around the Earth, and that insanity could be relieved by drilling holes in the skull to let the demons out? Have we also forgotten that Galileo, the great scientist who dared to say that the world was round, was persecuted for his effronteries to the scientific world of his time? And, Galileo lived some three centuries after the first statutory reference in Appendix A.

Unfortunately, various "experts" in every age, rooted in tradition, fight change, and developments in science, with deplorable results for public health.

It is well known that sailors of the British navy became known as "Limeys" because part of their diet after 1795 was lemon juice (then called lime juice), taken to prevent scurvy which had been a long-time dread killer. Not as well known is the story of Dr. James Lind, surgeon of the British fleet, who had performed experiments showing that scurvy could be prevented by a bit of lemon or lime juice added to the diet. In 1753 he published a book "A Treatise of the Scurvy", including recommendation of this item for the diet, promptly rejected by the notable Lords of the British Admiralty, who then considered that anyone showing the malaise which is associated with scurvy was nothing more than a "malingerer" requiring the "therapy" of a good flogging.

Following publication of his treatise, Lind's fellow physicians also attacked him. It was 42 years after Dr. Lind's treatise had been published that the British navy finally adopted the simple "ascorbic" regimen Dr. Lind had recommended. Now we know that the Vitamin C in the limes recommended by Dr. Lind is a vital and essential necessity for the diet of mankind.

The Federation urges that for the best "science" to insist that it knows Laetrile is worthless in every case is vainglorious presumption.

In the long upward struggle of man toward his enlightenment and progress from primitive savagery to the light of reason and understanding, countless multitudes of unfortunates have suffered from the persecution, indignities and tortures of their fellows. These persecutions have encompassed almost every field of human activity. For example, Copernicus, more lucky than Galileo, missed by a hair being burned at the stake because he taught that the Earth

was round, and was merely a satellite of the sun, rather than being the "center of the universe" as was then taught by the "great scientists".

Joseph Lister—nearly driven out of the medical profession by the British Medical Association because he said that surgery which was not antiseptic gave rise to infection and caused great mortality among patients. Lister in turn had merely followed the teachings of Louis Pasteur, the discoverer of the germ theory of disease.

Pasteur—nearly driven from his Chair at the University of Paris by the doctors and physiologists of France.

Semmelweis—and in United States Oliver Wendell Holmes, Sr., who discovered the cause of puerperal fever, resulting in death of women in child birth—the cause being the dirty hands of doctors—was nearly driven from the profession. Semmelweis died driven, disgraced, and hounded to his death. Semmelweis had merely insisted upon washing his hands after he came out of the dissecting room, before delivering a woman of child.

Dr. Jenner—developed the theory of practice of vaccination as a preventative, and also persecuted by the medical profession.

Dr. W. W. Keen—a student of Lister who came back to practice in Philadelphia, virtually driven out of practice by the medical association.

Robert Koch—developer of 606, who did work on tuberculosis—persecuted by the German Medical Association.

William Harvey—discoverer of the circulation of blood—persecuted by his colleagues.

Countless thousands of sufferers have died because of the ignorance of "current science" and the rigidity and

refusal to admit progress as to new therapies and medicine.

George Washington, the Father of our Country, when 67 years of age and in retirement in Virginia after his Farewell Address, rode out to inspect his plantation, and suffered a cold. The "current science" of his time was mustered, and he received massive bleeding, leeches, and other "remedies" now recognized as barbaric. George Washington succumbed several days later, not of his cold, but primarily due to the treatments rendered by the "medical experts" of his time. He had been denied a condemned minority treatment, which now would be "mandatory", according to current medical thought.

Indeed, orthodoxy thus indirectly killed the Father of our Country, though a life-saving treament was then in existence, but vetoed by the "learned" majority of practioners.

More recently, we have the example of Dr. Alexander Fleming, famous pioneer of penicillin, his discovery remaining on the shelf for twelve years while he was designated a "quack" by orthodox practitioners who merely did not understand what he was doing.

William James, father of American Psychology and himself a physician, aptly described the three stages encountered by any new treatment:

1. Entrenched orthodoxy calls it quackery and non-existent.

2. It is admitted to exist, but is written off as unimportant or useless.

3. Finally, its former foes exultantly claim "We helped discover it!"

CONCLUSION

In the case at bar, FDA has become an instrument of oppression against Respondent Rutherford and other innocent cancer sufferers who merely seek to cling to life, even to regain lost health through those therapies they desire to choose for their own bodies.

Permitting one group to become a state-endowed monopoly is as dangerous in the healing arts as it is in economics or in political thought—perhaps more so, for here we are dealing with life itself. Unfortunately man can be jealous of the known and reluctant to even consider what is new or different. History has shown that men of medicine and bureaucrats can be as narrow and uncompromising as other men. History has shown that many discoveries that we now consider significant were rejected by the majority and their discoverers hounded[11]:

The concept that an infirm person should have a constitutional right to choose any kind of medical treament available is not a new or modern invention.

Two centuries ago Dr. Benjamin Rush, renowned physician and surgeon general of the Continental Army of the United States, also a signer of the Declaration of Independence, stated that: "Constitution of this republic should make special provisions for medical freedom as well as religious freedom. . . . To restrict the art of healing to one class of men and deny equal privilege to another will constitute the Bastille of medical science. All such laws are

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[11] All of these circumstances are "overlooked" in Petitioner's "Appendix A".

un-American and despotic. They are fragments of monarchy and have no place in a republic."

As it today hounds Glen Rutherford, and others who desire Laetrile, FDA would yesterday have hounded a Lister, a Pasteur, a Jenner, a Koch, an Oliver Wendell Holmes, Sr., or Sir Alexander Fleming. And the day before it would have accused and prosecuted those who dared refuse to bleed during illness or use leeches. From this, progress does not come. From this, man in control may be more comfortable and secure in his comparative ignorance, but he does not learn.

In this context the instant case is of great significance to all Americans. Because of this significance, it is respectfully urged that this Court shall uphold the action of the Court below.

Respectfully submitted,

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Exhibit A